

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S. W. (Room 615F)
Washington, D. C. 20201

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Dear Secretary Shalala;

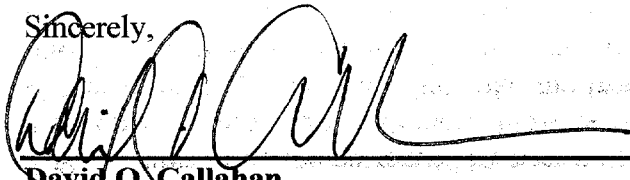
I am a small business owner in Hanford, California and I provide hearing health care to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would extensively increase the cost of hearing health care and dramatically reduce the access to hearing health care providers. Please, take time to consider the impact of this proposed hearing aid rule on the nation's hearing impaired and on the nation's small business health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new administration, FDA is rushing to put forth a proposal that could eliminate hearing aids specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a Consumer Guide to Hearing Aids, which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20% of those who need a hearing aid have one." Please so not let the FDA erect unwarranted barriers to this safe and effective medical device.

Please, do not let the FDA publish its proposed hearing aid rule.

Sincerely,



David O. Callahan
Hearing Instrument Specialist
License # HA3958

Miracle Ear
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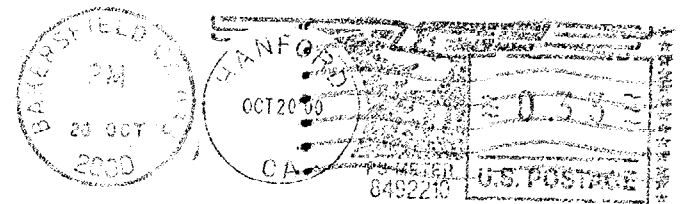
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HONORABLE DONNA SHAUALA
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